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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,844	10/23/2003	James R. Grabek	2980	6682

7590 03/01/2006

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EXAMINER

JOHNSON III, HENRY M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,844

Applicant(s)

GRABEK ET AL.

Examiner

Henry M. Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Arguments

Applicant's arguments filed 1/17/06 have been fully considered but they are not persuasive. Bertolero et al. disclose treating atrial fibrillation by ablating the epicardial surface of the heart from within the pericardial space. Kuo et al. clearly teach anchoring an end of an ablation catheter to tissue and moving the flexible portion to align the electrodes, specifically for treating atrial fibrillation. Thus, the method of accessing the pericardial space is known as is a method for anchoring and manipulating an ablation catheter.

Drawings

This application lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0120268 to Bertolero et al. in view of U.S. Patent 6,623,480 to Kuo et al. Bertolero et al. disclose a method for ablation of cardiac tissue for treating cardiac arrhythmias including contacting a device with epicardial tissue, using a tissue contacting member on the device to secure the device to the tissue, and ablating the tissue with an ablation member on the device. In some embodiments, the method further includes additional steps such as positioning the device on the epicardial tissue, stabilizing cardiac tissue, cooling cardiac tissue, positioning the device using a positioning device, visualizing epicardial tissue with an imaging device and/or the like (paragraph 0052). The ablation is disclosed as RF (paragraph 0059) and may be a single linear array (Fig. 4). The method includes positioning an insufflation device between the epicardial tissue and a layer of pericardial tissue and introducing an insufflation medium into the insufflation device to create a space between the epicardial tissue and the pericardial tissue (paragraph 0016). Clearly the pericardium must be intact for an insufflation procedure. Bertolero et al. do not teach anchoring the end of an ablation device and conforming the electrodes of a flexible portion onto the desired area. Kuo et al. teach a catheter and a related method for the treatment of atrial flutter utilizing radio frequency energy (Col. 1, lines 11-13) using a catheter that includes a screw-in anchoring device or anchoring hook located at the distal tip of the catheter. This device includes a corkscrew tip that is used to anchor the catheter at a preselected location during deployment, which advantageously allows the operator to bend or mold the catheter as necessary to place the electrodes at the desired target location (Col. 4, lines 35-41). The anchor may be a hook (barb) located at the distal end (Col. 4, lines 36-37). The catheter is anchored in cardiac tissue and the electrodes are

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positioned at the desired location for ablation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the flexible, anchorable ablation catheter as taught by Kuo et al. in the access method of Bertolero et al. to produce lesions on the epicardial heart surface. Epicardial access is known as is using RF energy to produce lesions in the treatment of atrial fibrillation. It is proper to take into consideration not only the teachings of the prior art, but also the level of ordinary skill in the art. In re Luck, 476 F.2d 650, 177 USPQ 523 (CCPA 1973). Specifically, those of ordinary skill in the art are presumed to have some knowledge of the art apart from what is expressly disclosed in the references. In re Jacoby, 309 F.2d 513, 135 USPQ 317 (CCPA 1962).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent Application Publication US 2004/0024435 to Leckrone teaches pericardial access for delivery of a catheter.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

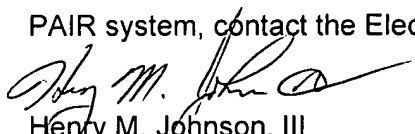
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Henry M. Johnson, III
Primary Examiner
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